Skanlab NG Pro™

OPERATING INSTRUCTIONS

© **Skanlab AS – Norge**

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Made in Norway

CE 0470

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Patent No. 179348, US Patent No 5.579.202, Trade Mark No. 178941

1.0 INTRODUCTION

Skanlab NG Pro™ is a medical device indicated for the treatment of soft and hard skeletal tissue disorders resulting from injury or degenerative processes. It was developed in Norway and was introduced to the market in 1988 under the brand - SKANLAB 25 BODYWAVE® . The instrument uses a 500 kHz high frequency AC current where the patient's own tissue is part of the capacitor, a diathermy treatment known as the Capacitor Field Method.

It is intended for use by clinicians and practitioners who have been professionally trained in diathermy such as physical therapists and chiropractors. It should only be used by trained professional personnel.

Please contact your local Skanlab representative or distributor who will arrange a product demonstration and training in the use of the **Skanlab NG Pro™**.

1.1 APPROVAL AND CERTIFICATES

CE 0470
The equipment complies with all requirements of the Medical Device Directive (93/42/EEC)

2.0 CHAPTER – SAFETY OVERVIEW

2.1 PRELIMINARY NOTES

It is important that you read these operating instructions carefully before using **Skanlab NG Pro™** Please make sure that these instructions are available to all personnel who operate the equipment.

Pay attention to the following before using the **Skanlab NG Pro™**;

1. Study the full list of contraindications and warnings (see chapter 3.0)
2. Do not touch the patient during treatment
3. Never leave the patient unattended during treatment
4. The apparatus may not be used in close proximity (i.e.less than 2 meters) to other equipment
5. The apparatus may not be used in so-called "wet rooms" (hydrotherapy rooms)

The manufacturer cannot be held responsible for the results of using this apparatus for any purpose other than described in these operating instructions.

2.2 GENERAL

When the unit is switched on all functions are controlled via a microprocessor.
During the functioning of the unit the actual output of the current is measured continuously

and compared to the requested output. If a fault is detected, the unit will switch off the current immediately.

2.3 EXCLUSIONS

Skanlab NG Pro™ is for treatment of soft and hard skeletal tissues only such as articulating joints, including the spine and skeletal muscle. It is not intended for treatment of any other internal tissues or organs. Please refer to Contraindications and Warnings in Chapter 3.

2.4 ELECTROMAGNETIC INTERFERENCE

Simultaneous connection of a patent to High Frequency Therapy equipment and an electrical stimulator must not be done this may result in burns at the site of the stimulator electrodes. Therefore, simultaneous connection is not allowed.

2.5 PRODUCT LIABILITY

A law on Product liability has become effective in many countries. This Product Liability laws implies, amongst other things, that once a period of 10 years has elapsed after the product has been brought into circulation, the manufacturer can no longer be held responsible for possible shortages of the product.

2.5.1 LIMITATIONS OF LIABILITY

To the maximum extent permitted by applicable law, in no event will Skanlab AS or its suppliers or resellers be liable for any indirect, special, incidental or inability to use the product, including, without limitation, damages for loss of goodwill, work and productivity, computer failure or malfunction, or any and all other commercial damages or losses, even if advised of the possibility thereof, and regardless of legal or equitable theory (contract, tort or otherwise)upon which the claim is based. In any case, Skanlab AS's entire liability under any provision of this agreement shall not exceed in the aggregate the sum of the fees paid for this product received by Skanlab AS under a separate support agreement (if any), with the exception of death or personal injury caused by the negligence of Skanlab AS to the extent applicable law prohibits the limitation of damages in such cases.

Skanlab AS cannot be held liable for any consequence resulting from incorrect information provided by its personnel, or errors incorporated in this manual and/or other accompanying documentation (including commercial documentation)

The opposing party (product's user or its representative) shall disclaim Skanlab AS from all claims arising from third parties, whatever nature or whatever relationship to the opposing party.

2.5.2 Service

Skanlab AS will Authorize Service persons and provide them with Servicemanual that connents "circuit diagrams, component part lists, descriptions, calibration instructions"

3.0 CHAPTER - CONTRAINDICATIONS

Do not treat patients with a pacemaker.

Do not treat patients with an infusion pump (eg insulin pump).

Do not treat patients who are pregnant (acceptable after first 6 months but not directly over foetus).

Hearing aids should be removed. Do not use in patient with cochlear implants.

Do not treat patients who have cancer.

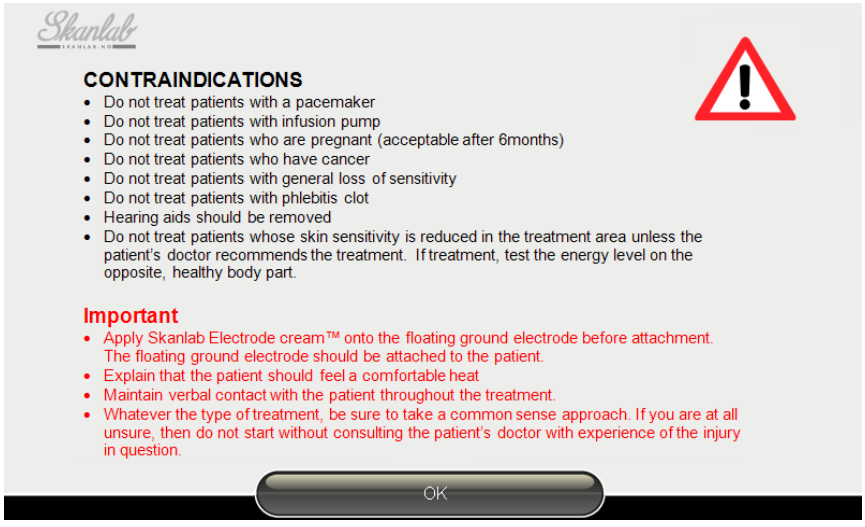
Do no treat patients with acute tuberculosis.

Do not treat patients with phlebitis clots (Deep Vein Thrombosis).

Do not treat patients with general loss of sensitivity or whose skin sensitivity is reduced in the treatment area unless the patient's doctor recommends the treatment. If treatment is indicated, test the energy level on the opposite, healthy body part where local insensitivity is a concern.

Haemorrhaging areas, that is skin with open cuts or partially healed wounds are contraindicated.

This contraindication information is visible in the display and must be accepted before treatment can commence.



3.1 IMPORTANT - WARNINGS

To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

Prior to treatment, patients should be asked about their general health and screened against the list of contraindications in Section 3.0 and any co-morbidities such as clotting disorders. Clots may become dislodged due to local thermal effects. Bleeding disorders may be impacted by increased heat and blood flow to treated areas. Care should be taken with patients taking anti-thrombotic medication such as warfarin and aspirin.

Whatever the type of treatment, be sure to take a common sense approach. If you are at all unsure, then do not start without consulting a physician, colleague, manufacturer or distributor with experience of the injury in question.

Skanlab NG Pro™ is for treatment of external tissues only. It should never be used internally in any body orifice.

Only touch the patient with the treatment probe during treatment. Do not touch the patient with your other hand as this could result in a change in electrical potential between patient and **Skanlab NG Pro™** device. This may cause an electric shock to you or the patient.

Do not use in a critical care environment. Electromagnetic radiation may impact critical care equipment.

Do not use in hydrotherapy rooms. Avoid contact of the electrodes and control unit with water during use.

Skanlab NG Pro™ therapy should not be applied to patients through clothing. Conductive material should be excluded from the treatment area.

The patient should not be allowed to come into contact with conductive parts which are earthed or which have an appreciable capacitance to earth which may provide unwanted pathways for the radiofrequency current; in particular, beds or chairs having metal frames should not be used.

Avoid having the applicator cables coming in contact with the patient, the therapist, or any conductive or energy-absorbent materials.

Only use the applicators and their cables as directed

Look after the insulation on probes and probe cables being careful to avoid damage. Do not use damaged cables or probes.

Only use **Skanlab NG Pro™** electrode gel as advised during the treatment.

During treatment, explain that the patient should feel a comfortable heat. Avoid excessive manual pressure which could be uncomfortable.

Maintain verbal contact with the patient throughout the treatment. Do not leave the patient alone and seek feedback on how they are feeling during treatment.

Other equipment connected to patient must be removed before the treatment starts.

Local skin conditions may become irritated by the application of the probes, for example eczema or psoriasis. If this happens, do not directly treat the area.

Avoid treating a patient who has just come in from the cold. Wait until the patient has returned to his or her natural body temperature in the area to be treated.

Care should be taken in treatment of menstruating women. The effects on blood flow, if any, are unknown.

When using to treat the spine, care should be taken to avoid the cervical-occipital joint which would require treatment of the head.

The apparatus may not be used in close proximity (i.e.less than 2 meters) to other equipment.

Do not install the unit in a location near to a heat source such as a radiator. Avoid exposure to sunlight, water and rain, excessive dust, dampness, mechanical vibration and shocks.

Should water enter into the control unit, disconnect from the wall socket and have it checked by an authorized agent.

4.0 CHAPTER - INSTALLATION

4.1 CONNECTION

- Mains supply connections must comply with the national requirements regarding medical rooms.
- Be sure to place the device for easily reach of main switch ON/OFF on rear side
- Prior to connection of this apparatus to the mains supply, check that the voltage and frequency stated on the type plate correspond with the available mains supply.
- Only the manufacturers approved mains cable is allowed for use.
- Only the manufacturers approved electrode cable and probe cable are allowed for use.
- Only use the Applied parts supported by Skanlab NG Pro defined as the floating ground electrode and treatment electrodes

4.2 SWITCHING ON AND SELF TEST

- Connect the mains cable to the connector and to the wall socket
- Switch on the unit, using the on/off switch on the rear side of the unit.
- Immediately after switching on, the unit carries out a self-test indicated on the screen.

4.3 DISCONNECTING FROM THE MAINS

- Switch the device off, using the on/off switch.
- Remove the mains cable from the wall socket

5.0 CHAPTER - OPERATION

5.1 TREATMENT – START

5.1.1 Skanlab NG Pro™ THE CAPACITOR FIELD METHOD

Applied parts, the floating ground electrode and treatment electrodes, are placed on opposing sides of the body area to be treated. The surface of the treatment electrode is non-conducting and the conductive part is separated from the skin by an insulating material. The treatment electrode is mounted on the treatment probe or handle . There are currently 2 diameter electrodes, 23 and 30 mm suitable for treatment of smaller or larger areas. The ground electrode is conducting and is non-insulating. The treatment electrode and ground electrode act as the plates of a capacitor, while the patient's tissue together with the insulated treatment electrode surface material form the dielectric. When current is applied, rapidly alternating charges are induced in the treatment electrodes and give rise to a rapidly alternating electric field between them. The electric field influences the materials which lie within it.

The Capacitor field method is dependent on:

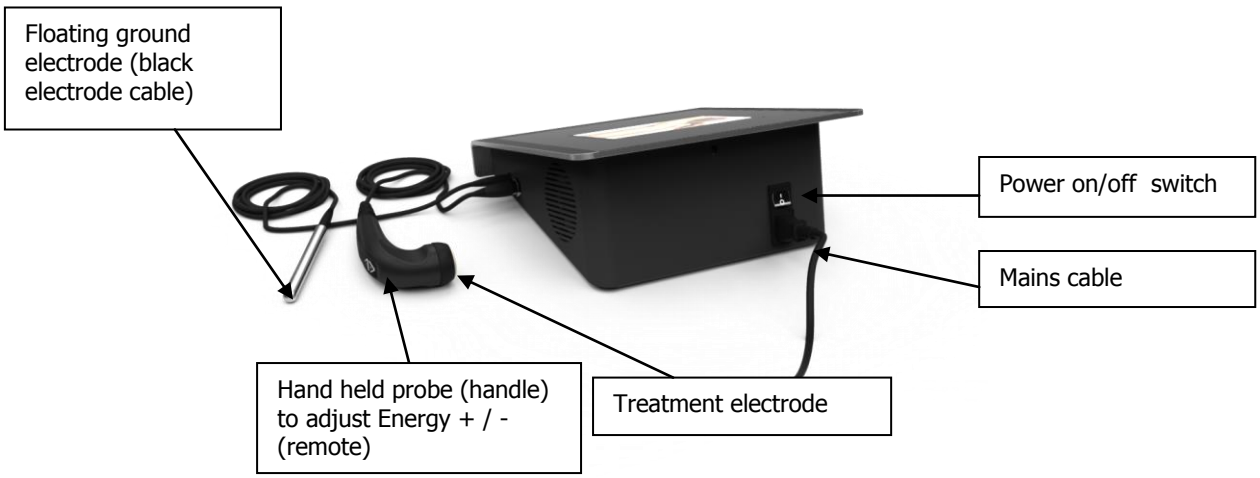
- The dimension of the capacitor plate of the treatment electrode (Ø23 and 30 mm).
- The distance between the two electrodes.
- The materials between the electrodes, including tissue/insulation/electrode gel.

It is therefore important to have the smallest possible distance between the area being treated by the probe and the floating ground electrode during the treatment.

There are currently 2 different sizes of treatment electrodes and the choice depends on the nature of injury, or strain.

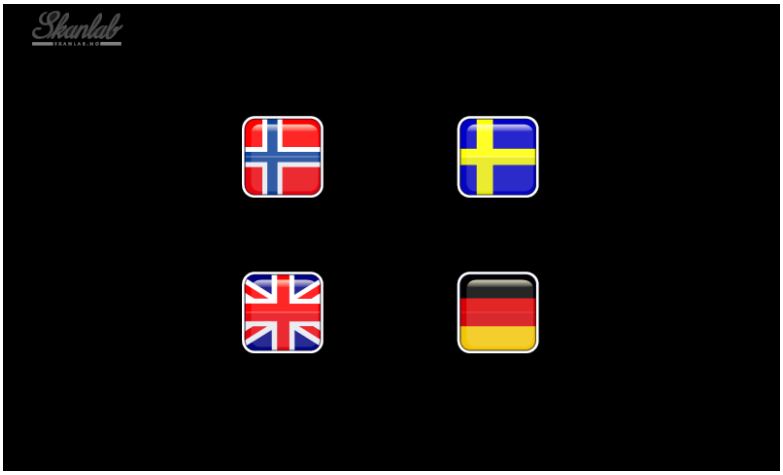
5.1.2 CONTROLS

Hand held probe (handle)
w/treatment electrode to adjust
Energy + / - (remote)
ON/OFF



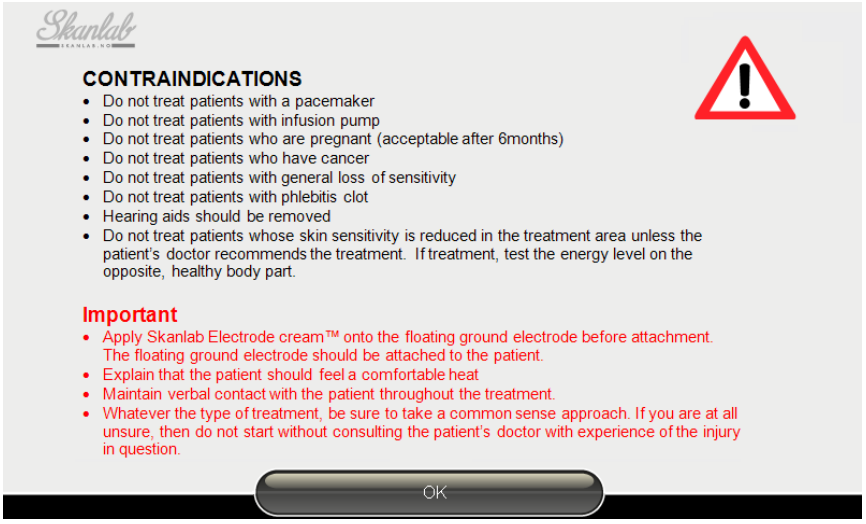
5.1.3 STARTING AND SELECTING TREATMENT

On turning on, the system goes through the following 2 screens automatically.



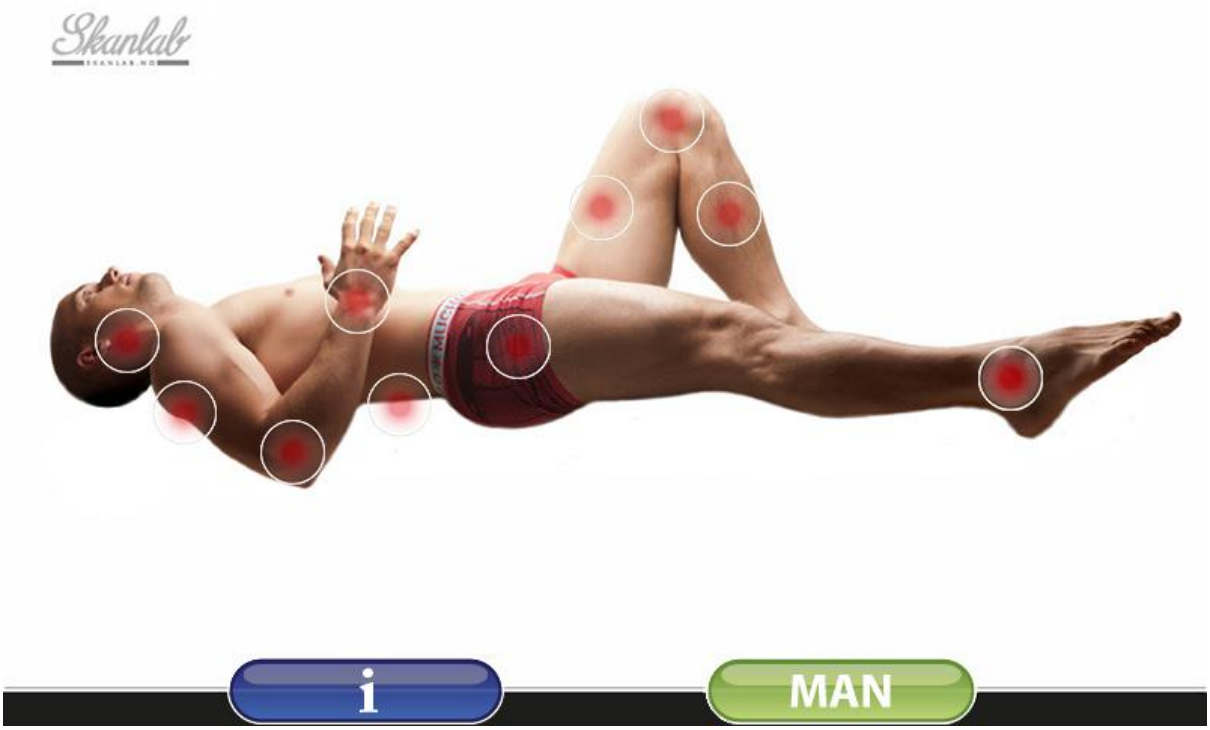
There are 4 language versions currently offered.

Once the language has been selected by pressing the touch screen symbol, the following screen is shown.

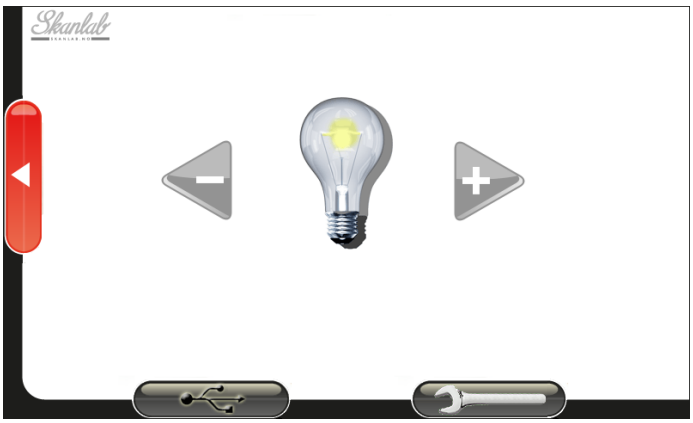


This screen is a reminder of the contraindications and warnings listed in the instructions for use. The operating modes cannot be accessed without pressing the OK button.

Once the OK button has been pressed the following appears:



The i symbol gives access to a screen below where screen brightness can be modified, depending on environmental conditions and user preferences.



This option also gives access to the service menu (only accessible by authorized service personnel, not by user, code access required).

In order to promote the best possible treatment with **Skanlab NG Pro™** we have endeavoured to set out the advice and experience of our own and other therapists using the method and incorporate these into a range of treatment menus. These are accessed

by pressing the anatomical locations on the above screen. Alternatively, a fully manual protocol can be used by selecting the MAN button on the touch screen.

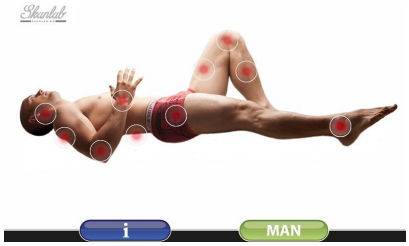
Remember that all treatment is individual, so try to create your own approach to therapy. Some rules have to be followed, of course, and we have sought to describe them here.

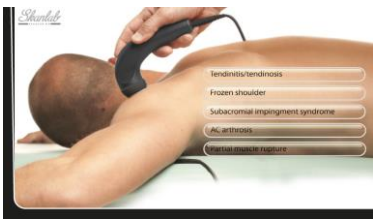
Additional points to consider:

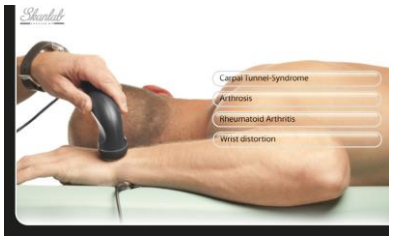
- ***Floating ground electrode***
  Choose the type of floating ground electrode that is most popular for the type of injury concerned (massive or disposable adhesive floating ground electrode). In most cases the patient will be lying down during treatment. In this case the massive can be placed under the patient.
- ***Treatment time (time)***
  Usually, treatment will be minimum 4 minutes, depending on the size of the injured area and the state of the injury.
- ***Intensity (energy).***
  The energy may vary from 1-10. Only seldom does the therapist use energy 1-2 or 7-10. Work fairly slowly and always and work down until the patient feels comfortable heat.
- ***Treatment electrode***
  The choice of the large or small treatment electrode is determined by the size of the injury. Back injuries require the larger electrode, finger injuries a smaller electrode. Remember that a large electrode needs more energy and that a small area requires less. Both the speed and the technique applied will determine how much energy to apply.

5.1.3.1 Menu Driven Treatment

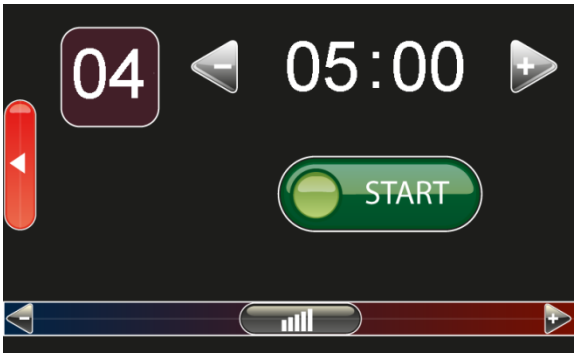
An anatomical location from the listed 10 sites is selected by the touch screen. The screens for all 10 locations are shown below.







The selected indication from the touch screen loads the recommended treatment parameters.. The time is given in minutes. Treatment is started by pressing START.



Once start is pressed, the treatment proceeds as indicated by this screen.

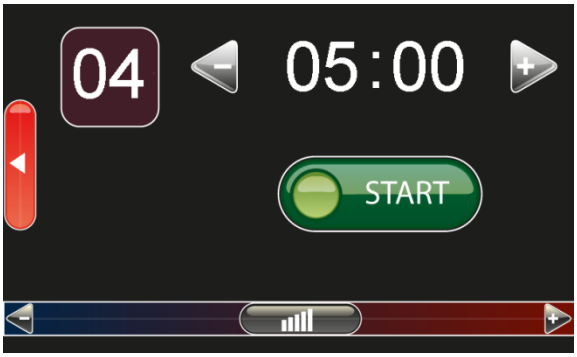
Treatment can be stopped anytime by pressing the STOP button. The clock counts down to zero until treatment is finished, shown by:

Once started, the treatment time cannot be extended.by using the + and – symbols in the time bar on the touch screen. Power can be adjusted by:

- Use of the probe power adjustment button.
- Pressing the + or – buttons on the power scale.
- Sliding the power bar button on the power scale left or right.

5.1.3.2 MANUALLY SELECTED TREATMENT

Selection of the Manual mode gives the following screen and no anatomical location is given.



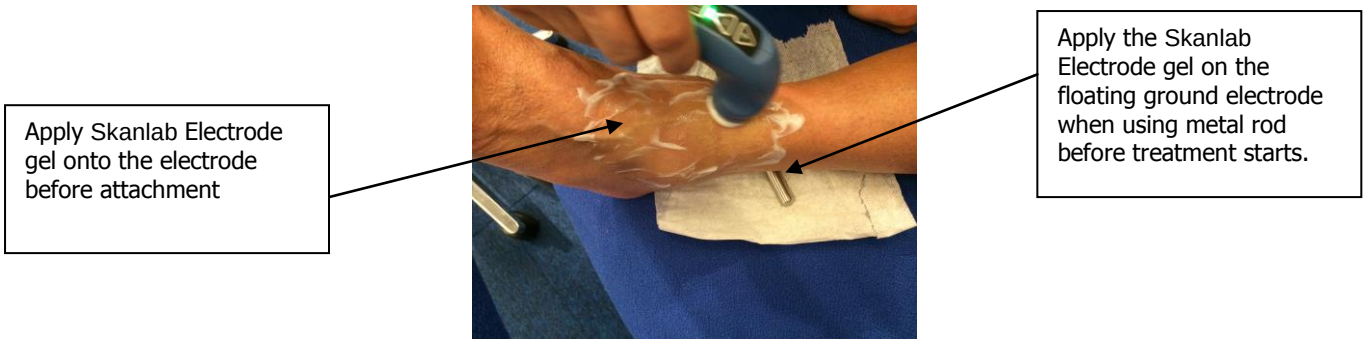
The time and power level (1-10) are selected manually and the START button pressed to initiate the selected treatment. Please note that Skanlab recommends never starting treatment above level 7. This can be adjusted upwards once feedback on comfort is obtained from the patient. Once complete, a FINISHED screen is shown.

5.2 APPLICATION OF PROBE AND ELECTRODE

We recommend to never start treatment at level 7-10, this may cause discomfort to the patient. It is recommended to start treatment at power level 3-7 and then adjust based on patient's feedback.

1. Uncover the skin in the area to be treated.
2. Apply the **Skanlab Electrode gel** on the area to be treated.
3. Apply the floating ground electrode to the opposite side of the treatment.
4. Use the screen menu or manual protocol to administer the treatment.

After treatment, disconnect the electrode and probe cables and clean the probe and electrodes with an alcohol based swab.



6.0 CHAPTER – MAINTENANCE

6.1 TECHNICAL MAINTENANCE

Check the electrode cables regularly for damage and/or bad electrical contact. We also advise that you keep an extra set of treatment cables in stock

We recommend that the unit is serviced annually. This may be done by your supplier, or by another agent, authorised by the manufacturer. It is also recommended that a record of the service history is kept for all activities relating to service and maintenance. In some countries this is even obligatory.

Maintenance and all repairs should only be carried out by an authorised agent. The manufacturer will not be held responsible for the results of maintenance or repairs by unauthorised person.

The service and/or maintenance must be carried out conform the procedure described in the service manual for the unit.

Opening of the equipment by unauthorised agencies is not allowed and will terminate any claim to warranty.

6.2 CLEANING THE CONTROL UNIT

Switch off the unit and disconnect it from the mains supply. Clean the apparatus using a cloth moistened with soap and water.

6.3 CLEANING THE ELECTRODES AND CABLES

Clean the electrodes and probes by wiping the surface with a standard alcohol based swab. Wipe with a tissue to dry or allow to air dry. The electrodes and probes should be cleaned both before and after use.

The disposable adhesive electrode is for single use only and should be disposed of after single use.

6.3. MAIN POWER FUSES

In case of power failure the main power fuses should be checked and changed by the owner.

1. Pull out the main power cable.
2. Pull out the fuse holder and change both fuses. Fuses; 2xT 2,5A H 250V
3. Replace the fuse holder and plug in the main power cable.
4. Turn on the machine and check the ON indicator.
5. If it still doesn’t work, contact your dealer.

7.0 STANDARD EQUIPMENT

61-4	Treatment electrode, Ø30mm	-	1
70-3	Hand-held probe (handle w/remote)	-	1
11-4	Floating ground electrode, massive	-	1
21.3600-4	Cable for floating ground electrode	-	1
21.3600-17	Main power cable	-	1
21.3600-6	Skanlab Electrode gel	-	1 ltr

7.1 ACCESSORIES

7.1.1 Electrodes

61-4	Treatment electrode, Ø30mm
62-4	Treatment electrode, 23mm
70-3	Hand-held probe (handle w/remote)
11-4	Floating ground electrode, massive

7.1.2 Cables, connectors and electrode gel

21.3600-4	Cable for floating ground electrodes
21.3600-6	Skanlab Electrode gel (1 lt.)
21.3600-13	Skanlab Electrode gel (5 lt.)
21.3600-11	Hand pump
21.3600-17	Main power cable
	2 Main power fuses (2xT 2,5A H 250V)

8.0 CHAPTER - SPECIFICATION

The anticipated in use life of Skanlab 25 NG pro is 10 years from first use. Probes and electrodes are subject to accidental damage due to storage or impact and should be checked prior to use for visible damage.

8.1 TECHNICAL SPECIFICATION

Mains voltage	100-240 VAC
Frequency	60/50 Hz
AC Output current	1,2-0,6 Amp
Maximum output power	24 W
Output frequency	500 kHz

8.2 UNIT

Medical device classification	IIa (according to MDD 93/42/EEC)
Safety class	I type BF, according to IEC 60601-1
Patient leakage current	better than IEC-req. (IEC≤ 100 μA)
Safety tests	Medical Electrical Equipment- Part 1; General requirements for safety
Dimensions	302x300x126,5mm (lxwxh)
Weight	4,3 kg

8.3 ENVIRONMENT CONDITIONS FOR TRANSPORT AND STORAGE

Environment temperature	: -10 till +40C
Relative humidity	: 10 till 90%
Atmospheric pressure	: 500 till 1060 hPa

8.4 ENVIRONMENT CONDITIONS NORMAL USE

Environment temperature	: 10 till +40C
Relative humidity	: 10 till 90%
Atmospheric pressure	: 800 till 1060 hPa

8.5 CLASSIFICATION AND STANDARDS

Classification of Skanlab 25 NG Pro

- Class IIa according to the Medical Devices Directive (MDD 93/42)

Software

- Class A according to EN ISO 62304: 2006, Software Safety Classification

Implemented Safety Standards

- IEC 60601-1: 2005+A1:2012 Medical Electrical Equipment – Part 1: General requirements for safety
- IEC 60601-1-2: 2007 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance – Section 2: Collateral standard: Electromagnetic disturbances -- Requirements and tests

- IEC 60601-1-4: 2002 Medical electrical equipment - Part 1-4: General requirements for safety - Collateral standard: Programmable electrical medical systems
- IEC 60601-1-6: 2010 Medical Electrical Equipment – Part 1: General requirements for safety – Section 6: Collateral standard: Usability
- IEC 60601-1-11: 2010 Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance – Section 11: Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- EN ISO 62304: 2006 Medical device software – Software life-cycle processes
- EN ISO 14971: 2007 Medical devices – Application of risk management to medical devices
- EN ISO 10993: 2009 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process

Manufacturing Standards

- EN ISO 13485: 2012 Medical devices – Quality management systems Requirements for regulatory purposes

8.6 SYMBOLS and ABBREVIATIONS

Symbol	Meaning
	Keep dry
	Manufacturer
	Serial number, including manufacturing date
	Refer to Operating Instructions
	Do not dispose with your general waste
	Type BF Applied Part
	Temperature transport conditions
CE 0470	The Device Complies with Medical Device Directive 93/42/EEC
	Safety Alert, Refer to Operating Instructions